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EXAMINER

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



## **DETAILED ACTION**

### ***Response to Amendment***

The reply filed on 4/23/08 is sufficient to overcome the drawing objection and is thus withdrawn. However, the 112 1<sup>st</sup> paragraph rejections are maintained because Applicant argues that the implant can be used if the rod is removed, but Applicant has failed to specifically point out the support in the original written disclosure for the implied claim limitations of the same procedure, i.e. “inserting a spinal implant with a rod connected to the vertebrae” (M.P.E.P. 714.02) or “removing the rod prior to inserting the spinal implant”. Because of the procedure outlined in M.P.E.P. 2163.06 for interpreting the claims, it is noted that other art may be applicable under 35 U.S.C. 102 or 35 U.S.C. 103(a) once the aforementioned problem under 35 U.S.C. 112, first paragraph, is corrected.

### ***Specification***

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the limitation that the rod is disengaged from the first and second bone screws was not found in the written disclosure.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the preparation of the vertebrae by possibly forming bores in the sidewall that receives the insertion members or screws, does not reasonably provide enablement for laterally forming slots in the first and second vertebrae. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. For example, how is it possible to form lateral slots if the sidewalls of the vertebrae receive the screws for the attachment of the elongate member, i.e. rod of which is attached to the lateral side spanning the vertebrae? The specification gives no inclination that the slots which are for an intervertebral implant are used in the procedure with the connecting rod apparatus.

Claims 31-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The disclosure does not describe the method of correcting spondylolisthesis as including the use of lateral screws and an elongate member or rod *in combination* with insertion of an implant **between** the vertebrae. How is this possible? If the lateral slots are formed for the implant, there is no safe area in the lateral sidewall then to receive the bone screws for the elongate rod or vice versa.

The claims recite both apparatus (implant and correction rod system) are inserted or used laterally, thus it is not possible to perform this with both sets of apparatus used laterally as claimed in claim 36. Regarding claim 37, the disclosure describes the insertion of the apparatus described above, but fails to describe removal of the apparatus. Regarding claim 40, the disclosure fails to describe that a rod is disengaged from the bone screws and then the same vertebrae having the bone screws has elongated recesses created to receive engagement members of an implant.

### ***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 12,13,17,21,31-35,38 are rejected under 35 U.S.C. 102(b) as being anticipated by Laurain (5108395). Laurain discloses a method for correcting a spinal condition having incorrect curvature by removing an intervertebral disc, col. 1, lines 25-30, col. 6, lines 49-52. The surgeon then inserts laterally into the sidewall of the vertebrae, clamps and bone screws, (Figs. 1,9) and then a connecting member **6** is joined to engage the clamps to span between the vertebrae. Laurain discloses that a rotating force is applied to the connecting member to rotate the vertebrae relative to one another, col. 3, lines 4-16, col. 7, lines 18-21,47-52. With respect to claim 13, the examiner is interpreting the claimed elements “prosthetic joint” in this way: an object between the vertebrae in the “joint” space. Claims in a pending application should be given their broadest reasonable interpretation. *In re Pearson*, 181 USPQ 641 (CCPA

1974). See also *In re Morris*, Fed. Cir. 1997 127 F3d 1048, 1054,1055. Thus, since Laurain illustrates (Fig. 8,9) a prosthetic graft **G** in the joint space, it can be considered a “prosthetic joint”. Regarding claim 21, it is inherent that the surgeon uses a wrench to rotate the screws having hex head sections. A surgeon cannot use his hands to do this. With respect to claim 33, it is known in the art that grafts promote fusion. Regarding claim 34, it is inherent that the graft will permit some articulation or motion (which can be compression) between the vertebrae. Since placement of the elongate member **6** is on the lateral side of the vertebrae, it can be considered a lateral approach.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Laurain '395. Laurain is explained supra. However, Laurain fails to disclose the implant is inserted laterally. It would have been obvious to one of ordinary skill in the art to insert the implant while performing the surgery in the patient to place the implant laterally into the patient before placing the elongate member onto the screws since this would not require any more incisions in the patient since the lateral side has been exposed. It is common sense that a surgeon would minimize the incisions a patient would require such that the healing is kept to a minimum.

Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Laurain '395 in view of Jacobson et al. (5382248) and Conchy et al. (6749612). Laurain is explained supra. However, Laurain fails to disclose disengaging the elongated member

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from the insertion members and removing it along with the insertion members from the sidewall of the vertebrae. Conchy et al. teach (Fig. 8) that rods **2,3** spanning between vertebrae can be removed, col. 6, lines 28-30. Jacobson et al. teach that bone screws can become loose and broken to require removal, col. 6, lines 16-26, col. 12, lines 11,12,35-45. It would have been obvious to one of ordinary skill in the art to remove an incorrect elongate member as taught by Conchy et al. and broken screws as taught by Jacobson et al. from the vertebrae inserted by the method of Laurain such that problems with the correction apparatus can be corrected if necessary.

Claims 31-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thomas et al. (6964665) in view of Laurain '395. Thomas et al. disclose (Fig. 7c) a spondylolisthesis correction system including bone screws **12** laterally inserted into first and second vertebrae and a connecting member or rod **50** is spanned between the vertebrae. Thomas shows the spondylolisthesis condition and discloses the system is used to correct this condition, col. 6, lines 45-51. The Examiner interprets the forces of rotation to move the vertebrae whether indirectly or directly are applied to the rod **50** and thus correcting of the deformity is accomplished. However, Thomas et al. fail to disclose that the spinal disc would need to be removed or to place an implant between the vertebrae. Laurain is explained above. It would have been obvious to one of ordinary skill in the art to remove disc material if necessary or degenerative as taught by Laurain when performing the procedure of Thomas et al. and inserting bone screws and a connecting member laterally such that no further damage or painful conditions continue and the degenerative area is stabilized. With respect to claim 21, it would have

been an obvious expedient to use a rotatable wrench to rotate the connecting member as such only involves routine skill in the art and would give the surgeon good torque to move the rod.

Claims 12,13,17,20,21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson (5591165) in view of Kapp et al. (4554914). Jackson discloses (Figs. 9A-C) a spondylolisthesis correction system including bone screws laterally inserted into first and second lateral sidewalls of the vertebrae and a connecting member or rod **1** is spanned between the vertebrae. Jackson also discloses the connecting member is rotated (Fig. 9B) and discloses the system is used to correct spinal deformities by rotation from a lateral approach since it is done in the sagittal plane, col. 10, lines 6-10,19-41. However, Jackson fails to disclose that the spinal disc would need to be removed or to place an implant between the vertebrae. Kapp et al. teach (Fig. 1) that a prosthesis is to be inserted into the intervertebral space that also used a bone screw and connector member that spans the vertebrae. Jackson additionally teaches that first an intervertebral disc is removed to define a space for an implant, col. 2, lines 46-48, col. 4, lines 17-20. It would have been obvious to one of ordinary skill in the art to remove disc material if necessary or degenerative as taught by Kapp et al. when performing the procedure of Jackson and inserting bone screws and a connecting member laterally such that no further damage or painful conditions continue and the degenerative area is stabilized. Regarding claim 13, the Examiner is not giving any special meaning to the term "joint" to limit the prosthesis since no structure is defined in the claim and is being read into the claim. Thus since, Kapp's device can



move it is a prosthetic "joint". With respect to claim 21, it would have been an obvious expedient to use a rotatable wrench to rotate the connecting member as such only involves routine skill in the art and would give the surgeon good torque to move the rod.

Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson '165 in view of Kapp et al. '914 as applied to claim 13 above, and further in view of Marnay (5314477). Jackson as modified by Kapp et al. is explained supra. However, Jackson in view of Kapp et al. fail to disclose laterally forming slots in the vertebrae for laterally extending keels on a bone substitute implant inserted between the vertebrae. Marnay teaches to form lateral slots in the vertebrae, col. 3, lines 7-13,17,18,48-50, col. 7, lines 37,52,53. Marnay also shows (Fig. 2) laterally-extending keels to fit in the slots prepared in the vertebrae. Marnay also illustrates (Fig. 1) the bone substitute implant maintains space between the vertebrae. It would have been obvious to one of ordinary skill in the art to use the teaching of Marnay to prepare slots for laterally-extending keels of a bone substitute implant and modify the device of Laurain incorporated into the method of Thomas et al. such that the vertebral engaging members that are part of the joint replacement device has a larger attachment surface area by using keels which would better stabilize the implant between the vertebrae and not be displaced.

Claims 18,19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson '165 in view of Kapp et al. '914 as applied to claim 17 above, and further in view of Wagner et al. (6030389). Jackson in view of Kapp et al. is explained supra. However, Jackson as modified by Kapp fail to disclose the type of screws used in the

surgical procedures. Wagner et al. teach that there are two types of screws used in spinal stabilization procedures, bi-cortical and uni-cortical and enable the surgeon to decide which to use based on the type of device the screws are used with, col. 1, lines 31-44. It would have been obvious to one of ordinary skill in the art to utilize either bi-cortical or uni-cortical as taught by Wagner et al. in the method of spinal repair with the spinal implant of Jackson in view of Kapp et al. such that the implantable screws and connectors remain in place and provide the proper alignment for the patient.

Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Thomas et al. '665 in view of Laurain '395 as applied to claim 31 above, and further in view of Marnay (5314477). Thomas et al. as modified by Laurain is explained supra. Laurain does disclose other bone substitutes can be placed between the vertebrae or an implant so long as it maintains the vertebral spacing, col. 7, line 1-6. However, Thomas in view of Laurain fail to disclose the laterally forming slots in the vertebrae for laterally extending keels on a bone substitute implant inserted between the vertebrae. Marnay teaches to form lateral slots in the vertebrae, col. 3, lines 7-13,17,18,48-50, col. 7, lines 37,52,53. Marnay also shows (Fig. 2) laterally-extending keels to fit in the slots prepared in the vertebrae. Marnay also illustrates (Fig. 1) the bone substitute implant maintains space between the vertebrae. It would have been obvious to one of ordinary skill in the art to use the teaching of Marnay to prepare slots for laterally-extending keels of a bone substitute implant and modify the device of Laurain incorporated into the method of Thomas et al. such that the vertebral engaging members that are part of the

joint replacement device has a larger attachment surface area by using keels which would better stabilize the implant between the vertebrae and not be displaced.

Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over as being unpatentable over Jackson '165 in view of Kapp et al. '914, in view of Marnay '477 and in view of Jacobson et al. (5382248) and Conchy et al. (6749612). Jackson and Kapp et al. are explained supra. However, Jackson fails to that a spinal disc is removed or that an implant placed in the disc space has the vertebrae created with elongate slots and to disengage the elongate member from the insertion members and removing it along with the insertion members from the sidewall of the vertebrae. Conchy et al. teach (Fig. 8) that rods **2,3** spanning between vertebrae can be removed, col. 6, lines 28-30. Jacobson et al. teach that bone screws can become loose and broken to require removal, col. 6, lines 16-26, col. 12, lines 11,12,35-45. Marnay is also explained supra. It would have been obvious to one of ordinary skill in the art to remove a degenerative disc as taught by Kapp et al. and to also use an implant with the rod correction system of Jackson and it is also within the skill of a surgeon to remove or disengage an incorrect elongate member as taught by Conchy et al. and broken screws as taught by Jacobson et al. from the vertebrae such that problems with the correction apparatus can be corrected if necessary. It is also within the skill of an artisan to use an implant that requires elongate slots to be created in the vertebrae as taught by Marnay as an obvious substitution to the implant suggested by Kapp with Jackson's system since it provides predictable results. A longer anchoring member (keel) is better stabilized than a single tooth as taught by Kapp.

### ***Response to Arguments***

Applicant's arguments filed 4/23/08 have been fully considered but they are not persuasive. Applicant argues that Laurain fails to disclose rotating the connecting member between the bone anchors. First it should be noted that the claim only requires a rotating force to be applied to the connecting member, but does imply that other elements can cause the vertebrae to be rotated relative to one another. Laurain clearly establishes a rotation force applied to the connecting member, the fact that it is indirectly is a moot issue since the claim language is comprising and does exclude the rotating locking plates that move the connecting member and vertebrae. The Applicant also argues that Laurain fails to disclose a wrench to rotate the connecting member. However, as mentioned above, the claim does not explicitly require the wrench to rotate the connecting member per se, but could cause rotation of screws applied into it. Applicant's drawings do not even show that a wrench would be applied to the connecting member.

Applicant's arguments with respect to claim 12 have been considered but are moot in view of the new ground(s) of rejection.

Applicants argue the rejection over Thomas and Laurain fails to establish obviousness because it is the opinion by the Applicant that no force is applied to the rod 50. However, the Examiner would like to point out claim 31 requires a force applied to the elongate member or rod to rotate the vertebrae. It does not state whether it is indirect or directly applied thereon. Thus, even if an indirect force is applied to the rod of

the Thomas device, it meets the claim. Second the limitation "substantially lateral approach" is broad and relatively unlimited in how it can be interpreted. Thus, when things are moved laterally they can be considered a "lateral approach".

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (9am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700  
/Brian E Pellegrino/  
Primary Examiner, Art Unit 3738